

REMARKS

Claims 1-30 are pending in the present application. No amendments are made herein.

35 USC §101

Claims 1-30 are rejected as being directed to non-statutory subject matter. It is noted that that the Examiner indicates the PTO's guidance is that a patentable process must either (1) be tied to another statutory class (such as a particular apparatus) or (2) transform underlying subject matter (such as an article or materials) to a different state or thing.

However, it is clear that such statement is overly limiting as *more recent* caselaw has been provided by the Court of Appeals for the Federal Circuit ("CAFC"), including the *en banc* decision of *In re Bilski*, Fed. Cir., No. 2007-1130, October 30, 2008. It is recognized that the CAFC quoted the same cases cited in the PTO's guidance in stating that "a claim is not a patent-eligible 'process' if it claims 'laws of nature, natural phenomena, [or] abstract ideas.' (Brackets in original.) (*Id.*, at page 6). The CAFC stated the "underlying legal question" is whether a claim to a process is unpatentable "because it claims only a fundamental principle."

The CAFC quotes the decision by the US Supreme Court in *Gottschalk v. Benson* (hereinafter "*Benson*") finding that a claimed method for converting data in binary coded decimal format to pure binary format was unpatentable as it would be tantamount to claiming the algorithm itself, whether performed on a computer or not. In other words, the claim would patent "*the formula* for converting BCD numerals." (Emphasis added). Yet, the CAFC in *Bilski* did not state the claims in *Benson* were unpatentable simply because they failed to transform an "article or materials," which the present Office Action would do.

Instead, the CAFC holds that the Supreme Court has stated a claim is surely patent-eligible under §101 if "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."

Beyond this, the CAFC quotes the Supreme Court's statement that "We do not hold that no process patent could ever qualify if it did not meet the requirements of our prior precedents." Accordingly, the CAFC states "we agree that future developments in technology . . . may present difficult challenges to the machine-or-transformation test, just as the widespread use of computers and the advent of the Internet has begun to challenge it in the past decade." This is the CAFC acknowledging that the use of computer and the Internet are challenging the

narrowness of the machine-or-transformation test, and both the Supreme Court and the CAFC acknowledging the test does not fully encompass all patent-eligible claims under §101.

Turning to the present application, it is believed that the claims 1) are tied to a particular machine or apparatus, 2) transform a particular article into a different state or thing, and 3) reach beyond simply claiming a formula and beyond simply claiming a fundamental principle.

As background, the present application is directed towards a computer-based system that eliminates many of the problems with identifying and applying for patient-specific assistance programs. Historically, it was difficult if not impossible for any person to be aware of all possible assistance programs. It was difficult if not impossible for any person to understand the nuances of the eligibility standards for assistance programs, particularly if they are only defined by what administrators of the program had done before. Further, it was difficult if not impossible for information collected from a patient to be considered in various permutations that is, the same fact or related facts may be expressed in different or even inconsistent manners by a single patient based on the manner in which a question is asked by either medical personnel or by assistance programs. Even after all that, there was still the issue of being able to properly supply information to a particular assistance program in the manner that the program expected.

The present application alleviates or eliminates these problems. A database of the programs and knowledge regarding the qualifications (including, for instance, administrative decisions regarding the programs) is collected. A user inputs patient information (i.e., information related to status and condition that would be relevant to qualifications), and the system compares the input patient information (and permutations thereof) against the qualifications. The system can then determine whether it is “likely,” based on the initial patient information, that an assistance program is available. The “likely” determination may be a logic and weightings based analysis described in the specification, as opposed to a simple and precise ‘formulaic’ view of eligibility.

Claim 1 is tied to a particular machine or apparatus, as it specifically recites “computer-implemented method.” Claim 1 requires the logic steps of “based on [] initial patient information, making an initial determination as to whether it is likely that benefits can be obtained for the patient under an assistance program.” Based on the initial determination, there may be a further logic step of determining whether it is likely that benefits may be obtained under the assistance program. Accordingly, it is clear that claim 1 is hosted on a computer

capable of a logic-based comparison of the information from the patient to one or more assistance programs to identify a “likely” eligibility, and continues with a further logic-based comparison.

Claim 1 further transforms a particular article into another state or thing. More precisely, the claim describes a system that receives patient information, and transforms that information into a completed application. Claim 1 requires the system to “complete an application,” more specifically the step of “at least one of submitting the completed application to the assistance program and providing a copy of the completed application for submission to the assistance program.” Therefore, claim 1 describes not just a transformation, but an actual creation of a document, and envisions the submission of the document.

Claim 1 finally is clearly beyond simply claiming a formula or fundamental principle. The field of the art has not defined formula: such is one of the exact problems addressed, the inability to identify and determine eligibility for assistance programs by a particular patient, and the frustration that follows. If an exact or defined formula were available, the steps of “likely” would not be necessary.

The system is not like a binary conversion, or a tax accountancy program where numbers and binary answers are provided in order to generate a tax return: instead, the computer-implemented method necessarily makes judgments. That is, the “determination” is comparing the information against criteria in order to determine that it is “likely.” This “likely” aspect is stressed and further clarified in dependent claims, such as claim 4 in which the step of the initial determination is comparing information to “a well-established criteria for the assistance program,” and such as claim 7 requiring a “probability model.”

Similarly, claims 13 and 22 each recite a “computer-implemented” method including steps of “determining,” “comparing . . . information to a well-established criteria associated with” the program, and resulting in the answer to “likely” to qualify. Claim 22 explicitly recites use of a probability model.

Therefore, for the reasons discussed above, claims 1, 13, and 22, as well as the dependent claims therefrom, are eligible under §101.

35 USC §103

The cited and applied references are as follows: "Indicare – On-line Patient Assistance Program Website Users Manual," herein after "Indicare," U.S. Patent Nos. 4,491,725, to Pritchard ("Pritchard"), and 4,975,840, to DeTore, et al., ("DeTore"), and U.S. Published Application No. 2002/0107849, to Hickey, et al. ("Hickey").

Detailed in Applicants' previous response, the Office Action is incorrect regarding the teachings of Indicare. The Indicare document is a computer application manual for medical facility personnel to use a computer application to support a pharmacy's efforts to recoup drugs given away for free. The application is an interface with a database allowing a user to log into the system and identify whether a specific drug or pharmaceutical is subject to a reimbursement program, yet provides no benefit over searching the Internet for their drug and a logic expression such as "patient assistance" or "free" or "indigent," as examples. If a program is available, the application either a) provides a form from the database or b) indicates that there is an assistance program but no form can be provided from the database.

With respect to the presently invention, Indicare does nothing more. Indicare may create a patient record, but a patient's information is entirely irrelevant and is never transmitted in a request for replacement drugs. Indicare performs no analysis of patient information, and the application never generates a completed application, features explicitly required in the claims.

Pritchard mentions submitting claims to insurance carriers and to Medicaid, such is much different than the claimed invention: for insurance carriers and Medicaid, the patient is already enrolled in the program. The present invention identifies programs that may provide assistance based on "patient information," while Pritchard relies on programs that are already known to the patient because the patient is already an enrollee. Therefore, any "determination" possible by Pritchard is not whether it is "likely that benefits can be obtained," as required by claims 1, 13, and 22, instead the determination is to whom to send a claim.

DeTore is basically inapplicable to the present invention. DeTore is a very basic computer-implementation of risk assessment for insurance purposes. To be clear, such is not to determine "eligibility" for insurance, per se, as much as DeTore is focused on evaluating information in a database against information specific to an insurable risk (such as a building or a person). Elements of the information are correlated and weighted, and a providing a risk classification based on such correlation and weighting.

The Office Action utilizes DeTore to show that probability models are known in insurance arts; however, such statement appears to mischaracterizes the present application as being in the insurance arts. The present application has nothing to do with the “insurance” aspects of DeTore, as DeTore is trying to quantify and assess the risk of an insurable entity (termed in DeTore as “an insurable risk”). The present application does not assess any “risk” whatsoever. Accordingly, the relevance of DeTore is only to show that a “probability” model is not, in and of itself, new.

Hickey is, first and foremost, non-analogous art. There is no demonstration of why anyone would look to a system for searching for scholarships for teachings to address identification of patient assistance programs. For instance, once eligibility under a patient assistance program is established, the patient will in all likelihood receive benefits. For scholarships, eligibility being established merely means that an applicant is one of many applying for a limited number of scholarships. In such a sense, it should be recognized that a determination of eligibility is quite different in the fields of patient assistance programs and of scholarships. Additionally, it is clear that the application of Hickey in the present context would be impermissible hindsight.

Beyond this, Hickey fails to teach or suggest many of the elements of the claims. For instance, while Hickey requires the input of information, the results listed make no determination of eligibility. In fact, Hickey describes a paid preferences where scholarship companies that pay a fee get ranked higher in the results. The closest Hickey comes to the claimed steps related to, loosely termed, ‘determining likely eligibility’ are Hickey’s “ranking the scholarships . . . for how closely the scholarship searcher matches the scholarship’s requirements.” At no point does Hickey actually teach the step of ‘scholarship searcher would likely receive assistance from this scholarship organization.’ Finally, the system of Hickey fails (as do each of the other references) to actually create and either submit or provide a completed application.

The current rejection presented in the Office Action differ from those of the previous Action as follows: claims 1-6 and 9-12 were rejected as obvious in view of the combination of Indicare and Pritchard, now rejected in further view of Hickey; claims 7-8 were rejected in view of Indicare, Pritchard, DeTore, now rejected in further view of Hickey; claims 13 and 17-21 were and continue to be rejected in view of Indicare and Pritchard; claims 14-16 and 22-28 were and

continue to be rejected over Indieare, Pritchard, and DeTore; and claims 29-30 were rejected over Indieare in view of Official Notice, now over Indieare in view of Admitted Prior Art.

Turning to claims 1-6 and 9-12, as discussed above, claim 1 makes an initial determination, and, if the first determination is satisfied, a second determination. Indicare makes no analysis or determination other than whether the drug is listed in the database for reimbursement, and contains nothing to suggest that any other information that may be requested is used for any purpose related to qualifications for an assistance program or applying for an assistance program. The Office Action attempts to find “initial patient information” being obtained in Indicare, though it is clear that the claimed “patient information” is condition-type information, that Indicare requires no information, and that, regardless of whether Indicare obtains such information, there is no step of “determining” anything based on the obtained information. The only information Indicare requires or uses is the drug information.

For the Office Action to find the listed claim elements (pages 4 and 5) taught or suggested or otherwise made obvious by Indieare, the claimed “the initial patient information” would have to be the mere existence of a person having a name, and the claimed “initial determination” would be based on the person’s presence in front of the Indieare user or pharmacy personnel. Furthermore, as the only other information is the name of the drug, such must be the “additional patient information,” and the second determination would be whether a program for drug reimbursement exists for such drug. First of all, it does not make sense to suggest that a “determination” is based on a person’s name (the claimed “initial patient information”), and the “additional patient information” cannot be drug information, as the latter is not information about the patient. Moreover, any ‘determination’ made by Indicare is a binary choice – either the drug is reimbursable, or it is not: there is no ‘likely’ answer, unless ‘likely’ is meant to mean “certainty.” It is noted that a “certainty” answer would likely not satisfy the Supreme Court’s interpretation of §101.

When Indieare is combined with Pritchard, and Hickey, these features are still not taught or suggested. As discussed, Pritchard is directed towards a system where eligibility is already determined. Therefore, the system does not attempt to ‘determine’ whether eligibility is ‘likely.’ While Hickey does attempt to determine an eligibility, that eligibility not being a certainty, it still does not determine a ‘likely eligible for benefits.’ This is demonstrated by the above discussion

of the difference between scholarships and patient assistance programs where the former defines eligibility as being one of many that may or may not receive a limited number of scholarships.

Finally, no combination of the cited references teaches a computer-implemented method, as claimed in claim 1, to perform the step of “at least one of submitting a completed application to the assistance program and providing a copy of the completed application for submission to the assistance program.” Indicare simply creates a proprietary record of information, stored in its local database, and provides a separate form where one is available that can then be filled out in a traditional manner, and none of the other references of record teach such a system.

It should be noted that the difference between the previous Final Office Action rejection of claim 1 and the present rejection is the addition of Hickey. Similar arguments to the above were previously presented, the result being the addition of Hickey. The response to Applicants' arguments in the current Office Action includes the statement that Applicants rely on features not present in the claims (pages 15-16) such as “the computer application creates a record of whom the patient is.” However, the previous response explicitly stated that Indicare does exactly that. Furthermore, the Office Action fails to address how Indicare makes a ‘determination’ based on the patient’s name, or how the patient’s drug is patient information. In short, the Office Action simply fails to address how Indicare supports the claim limitations discussed above. Instead, the Office Action states an additional reference is provided, yet that reference also fails to teach or suggest the claim limitations, and the Office Action makes no attempt to apply the additional reference to address the arguments about Indicare’s shortcomings.

The Office Action state it is conceded that Indicare determines whether a drug qualifies for reimbursement. While this is correct, there is no ‘determination’ based on ‘patient information,’ and no second ‘determination’ based on ‘additional patient information.’ The Office Action states there are no parameters for qualification or the determination process: the Applicants’ have not argued that Indicare (or any other reference) fails to disclose or suggest specific parameters, other than the fact that the input information is most certainly “patient information,” which is most certainly not a factor in the Indicare document.

Lastly, the Office Action states “the computer generates a completed application” is not recited in the rejected claims. Applicants direct the Examiner’s attention the last phrase of claim 1 in which the “computer-implemented method for identifying and applying for benefits” includes the step of “at least one of submitting the completed application to the assistance

program and providing a copy of the completed application for submission to the assistance program." It is not clear how the Examiner interprets such as not reciting a generated completed application.

As the combination of references cannot make obvious claim 1, they similarly fail to make obvious any or each of the claims dependent therefrom.

Turning to claims 7-8, each of these claims is dependent from claim 1. Rejection of these claims adds DeTore to the references applied to claim 1, specifically Indicare, Pritchard, and Hickey. DeTore fails to teach or suggest the above-discussed limitations of claim 1. More importantly, the combination of references including DeTore does not teach or suggest or otherwise make obvious claim 1, as a whole, regardless of the teachings of DeTore with respect to claim 7. It should also be noted that the Office Action purports to find obvious a system for determining likely benefits and applying for same by combining a computer manual for searching for non-patient-specific drug reimbursement programs, an insurance risk model, a scholarship search program, and a Medicare claim submission program. In any event, the Office Action is engaging in impermissible hindsight by attempting (unsuccessfully) to cobble together various references from different art fields, yet still fails to even identifying all of the elements of the claims.

For claims 13 and 17-21, these stand rejected under the same grounds as previously provided. As discussed above, the Office Action fails to address how the noted limitations of claim 13 are disclosed or otherwise made obvious, nor how the claim in its entirety is made obvious by Indicare and Pritchard

Claim 13 is also a computer-implemented method in which initial "patient" information is collected, the information is compared to "well-established criteria," collecting additional "patient" information if the criteria are satisfied, and making a second comparison to eligibility requirements, both comparisons being specific to Medicaid, and providing an application if the eligibility requirements are satisfied. As stated above, Indicare makes no such determinations other than presence of a program for a drug, and does not make a determination by "comparing the initial patient information to a well-established criteria." While Pritchard makes mention of submitting claims to insurance carriers and to Medicaid, such is much different than the claimed invention: for insurance carriers and Medicaid, the patient is already enrolled in the program. The present invention identifies programs that may provide assistance based on "patient

information," while Pritchard relies on programs that are already known to the patient because the patient is already an enrollee. Therefore, any "determination" possible by Pritchard is not whether it is "likely that benefits can be obtained," as required by claim 13 as well as claims 1 and 22, instead the determination is to whom to send a claim. Accordingly, the combination of art fails to make obvious claim 13 as a whole, and therefore fails to make obvious claims 17-21, dependent therefrom.

Claims 14-16, dependent from claim 13, were and continue to be rejected over Indicare, Pritchard, and DeTore. Again, the addition of DeTore fails to make obvious the above limitations, or the claim as a whole. As Indicare simply fails to teach that which the Office Action alleges, and the combination of references fails to supply or otherwise make obvious many of the limitations of the claims, let alone make obvious the claim as a whole, the combination of Indicare, Pritchard, and DeTore cannot and do not make claim 13 obvious. For at least that reasons, claims 14-16 are not obvious in view of the combination.

Claims 22-28 were and continue to be rejected over Indicare, Pritchard, and DeTore. Again, Indicare fails to disclose that which the Office Action alleges, and the combination of art fails to supply or otherwise make obvious the limitations or the claim as a whole. Claim 22 generally incorporates many if not all of the points discussed above, but also describes determinations for first and second assistance programs. The present invention contemplates a computer-implemented method in which the initial patient information is screen or sorted against a plurality of assistance programs. Claim 22 makes this explicit. In contrast, Indicare screens to see if a particular drug is supported by a reimbursement program to recoup free giveaways, and Pritchard simply submits claims for patients that are already enrolled in specific assistance programs (such as insurance or Medicaid). DeTore does nothing to supply the missing elements.

Claims 29-30 were rejected over Indicare in view of Office Action, now over Indicare in view of Admitted Prior Art. Claims 29 and 30 are dependent from claim 13. The Office Action does not even attempt to find claim 13 obvious in view of Indicare and Admitted Prior Art, so this rejection is clearly improper. Additionally, claims 29 and 30 are not obvious in view of the applied art for claim 13 for at least the reasons discussed for claim 13.

In light of the above, Applicants respectfully submit that the cited references do not, either singly or in any combination, make obvious the limitations of any of the independent

claims 1, 13, and 22, as amended. Therefore, each of these claims and their dependent claims is believed to be patentably distinguished and in condition for allowance.

Accordingly, Applicants respectfully request a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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